REMARKS

Pending Claims

Claims 18 and 24-25 are currently pending. Claims 19-23 are withdrawn. Claim 18 has been amended. Claims 26-29 are submitted herewith.

Claim 18 has been amended to recite:

"A computer-based system ... for ... statistical prediction of binary outcomes, <u>said system comprising a processor, an input, an output, and a computer-readable storage medium; wherein the processor generates a tree model using Bayesian analysis,</u>
<u>wherein the processor generates a tree model using Bayesian analysis,</u> ... the tree model ... <u>comprising</u> one or more nodes representing metagenes predictive of lymph node metastasis, and one or more nodes representing clinical risk factors<u>;</u>
<u>wherein the metagenes are generated by sorting expression data from a plurality of genes into a plurality of clusters and extracting a singular dominant factor from each cluster using singular value decomposition,</u>
<u>wherein the processor generates a predicted disease outcome for a subject using the tree model; and</u>
<u>wherein the predicted disease outcome is displayed on the output.</u>"

Support for this amendment can be found at least on p. 31, line 22 through p. 32, line 16 and p. 57, line 11 through p. 59, line 18 of the originally-filed specification.

Support for the new claims can be found in the originally-filed claims and Abstract.

No new matter is added.

Telephone Interview Summary

On September 18, 2008, the Examiner and counsel for Applicants, Thomas J. Keating and Jeffrey D. Peterson, conducted a telephone interview in this case. The Examiner and counsel for Applicants discussed possible claim amendments to overcome the pending Section 101 subject matter rejections. No agreement was reached during the call. Counsel for Applicants gratefully acknowledge the Examiner's granting of and participation in the interview.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 18, 24 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. In particular, the Examiner contends that the language of claim 18 reciting "the statistical prediction" lacks antecedent basis.

Without conceding the substance of the rejections, Applicants have amended claim 18. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 101

Claims 18, 24, and 25 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. In particular, the Examiner contends that the claims are drawn to a computer model and that this is a form of data, and that data does not fall within one of the statutory classes of Section 101.

Applicants have amended claim 18 to recite: "A computer-based system ... for ... statistical prediction of binary outcomes, said system comprising a processor, an input, an output, and a computer-readable storage medium; wherein the processor generates a tree model using Bayesian analysis," which constitutes proper subject matter under Section 101. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 103

Claims 18, 24, and 25 stand rejected under 35 U.S.C. § 103(a) as being obvious over Buntine (Statistics and Computing (1992) Volume 2, pages 63-73) in view of Veer et al. (Nature (January 2002) Volume 415, pages 530-536).

Claim 18 has been amended to better define the invention, by reciting that "metagenes are generated by sorting expression data from a plurality of genes into a plurality of clusters

and extracting a singular dominant factor from each cluster using singular value decomposition." Buntine provides a general overview of Bayesian tree analysis but does not teach or suggest trees having nodes representing metagenes, and Veer et al. does not supply this deficiency.

Veer et al. presents several analyses of gene expression data and correlation of this data with disease outcome. However, Veer et al. fails to teach or suggest the use of metagenes. Veer et al. teaches grouping together genes based on expression levels (Fig. 1; p. 530, col. 2), but does not apply any subsequent mathematical analysis to the groups. In a different analysis, Veer et al. assigns correlation coefficients, but only to individual genes (Fig. 2; pp. 531-533). Veer et al. does not teach or suggest "sorting expression data from a plurality of genes into a plurality of clusters and extracting a singular dominant factor from each cluster using singular value decomposition."

As explained in the present application, extracting metagene data from gene arrays has several advantages:

> The evaluation and summarization of large-scale gene expression data in terms of lower dimensional factors of some form is utilized for two main purposes: first, to reduce dimension from typically several thousand, or tens of thousands of genes to a more practical dimension; second, to identify multiple underlying 'patterns' of variation across samples that small subsets of genes share, and that characterize the diversity of patterns evidenced in the full sample.

Page 57, lines 14-19 of the originally-filed specification.

Thus, because Veer et al. fails to supply the deficiencies of Buntine, the combination of Buntine in view of Veer et al. does not render claim 18 obvious.

The remaining claims are allowable at least because each depends from an allowable independent claim.

In view of the arguments and amendments presented herein, Applicant respectfully submits that the rejections have been traversed. Accordingly, Applicant respectfully requests that the rejections be reconsidered and withdrawn.

CONCLUSION

In view of the remarks and amendments presented herein, reconsideration and withdrawal of the pending rejections and allowance of the claims are respectfully requested. The Examiner is strongly encouraged to contact the undersigned at the phone number below should any issues remain with respect to the application.

Respectfully submitted,

/thomas j. keating/

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